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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,547	08/27/2003	Carsten-Peter Carstens	25436/1243	5516

27495 7590 06/29/2006

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EXAMINER

MCGILLEM, LAURA L

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/649,547	<b>Applicant(s)</b> CARSTENS, CARSTEN-PETER	
	<b>Examiner</b> Laura McGillem	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-10, 12-16 and 18-19 is/are allowed.
- 6) ☒ Claim(s) 1-3, 11 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

It is noted that claims 1, 4, 7-8, 12-14 and 19 have been amended in the response filed 2/27/2006. Claims 1-19 are under examination.

### ***Oath/Declaration***

It is noted that a substitute Declaration has been submitted on 2/27/2006 and has been accepted.

### ***Drawings***

The drawing (Figure 2) was received on 2/27/2006. This drawing is acceptable.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is being maintained for reasons of record in the previous Office Action, mailed 8/24/2005 and for reasons outlined below.

Applicant has amended claim 1 to clarify that the presence of a Rep protein in the host cell functions to initiate rolling circle replication at the double stranded origins of replication by substituting "at" for "as" following the phrase "wherein said host cell

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further expresses a gene encoding a Rep protein that can initiate replication", and by inserting the phrase "rolling circle" immediately preceding the word "replication".

Applicants submit that the present invention provides a method of transfer of a gene of interest from a first vector to a product vector comprising generating a fused vector (the co-integrate vector, described hereinabove) comprising the first vector and a second vector, followed by rescue of the product vector from the fused vector by rolling circle replication. The Rep protein is involved in the rescue of the product vector from the fused vector by causing the initiation of rolling circle replication. Applicants submit that rolling circle replication is illustrated in Figure 2. Applicants submit that any sequence located between two double-stranded origins of replication can be converted into a circular plasmid in a host strain providing the incising protein described above, providing a single-stranded origin or replication is present on the (+) strand.

Applicant's arguments filed 2/27/2006 have been fully considered but they are not persuasive. The amendment to claim 1 establishes that Rep protein can initiate rolling circle replication. However, as claim 1 is written, the method comprises introducing a first and second vector into a prokaryotic host cell which expresses a gene encoding a site specific recombinase and a gene encoding a Rep protein to initiate rolling circle replication. The further limitation of rolling circle replication by the Rep protein still does not provide a functional link between the Rep protein and formation of a product vector from the first and second vector. As claim 1 is written, it is unclear how Rep-initiated rolling circle replication on two separate vectors (i.e. the first and second vector) would produce the product vector as claimed.

Claims 11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a NEW rejection.

Although claim 11 was previously indicated as allowable in the Office action mailed 8/24/2005, on further consideration, new grounds of rejection have been applied.

Claim 11 is vague and indefinite because it recites the phrase, "a second selectable marker" and since there is no other selectable marker recited in this independent claim, it is unclear how the selectable marker is a "second" selectable marker.

Claim 17 is vague and indefinite because it is dependent on claim 12 or 13 and recites the phrase "further comprising a secondary host cell", but claims 12 and 13 do not recite a host cell and it is unclear how the recited cell would be a "secondary" host cell. It is noted that claim 14 is dependent on claims 12 or 13, and recites the limitation of a kit comprising a primary host cell. However, claim 17 does not depend from claim 14 and does not include the limitation of a primary host cell.

### ***Conclusion***

Claims 4-10, 12-16 and 18-19 are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem, PhD  
6/26/2006



**DANIEL M. SULLIVAN**  
**PATENT EXAMINER**